subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2305, Jan. 14, 2000]

§ 862.1117 B-type natriuretic peptide test system.

(a) *Identification.* The B-type natriuretic peptide (BNP) test system is an in vitro diagnostic device intended to measure BNP in whole blood and plasma. Measurements of BNP are used as an aid in the diagnosis of patients with congestive heart failure.

(b) *Classification.* Class II (special controls). The special control is ''Class II Special Control Guidance Document for B-Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers.''

[66 FR 12734, Feb. 28, 2001]

§ 862.1118 Biotinidase test system.

(a) *Identification.* The biotinidase test system is an in vitro diagnostic device intended to measure the activity of the enzyme biotinidase in blood. Measurements of biotinidase are used in the treatment and diagnosis of biotinidase deficiency, an inborn error of metabolism in infants, characterized by the inability to utilize dietary protein bound vitamin or to recycle endogenous biotin. The deficiency may result in irreversible neurological impairment.

(b) *Classification.* Class II (special controls). The special control is sale, distribution, and use in accordance with the prescription device requirements in § 801.109 of this chapter.

[65 FR 16521, Mar. 29, 2000]

§ 862.1120 Blood gases ($P_{CO}2$, P_O2) and blood pH test system.

(a) *Identification.* A blood gases ($P_{CO}2$, P_O2) and blood pH test system is a device intended to measure certain gases in blood, serum, plasma or pH of blood, serum, and plasma. Measurements of blood gases ($P_{CO}2$, P_O2) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.

(b) *Classification.* Class II.

§ 862.1130 Blood volume test system.

(a) *Identification.* A blood volume test system is a device intended to measure the circulating blood volume. Blood volume measurements are used in the diagnosis and treatment of shock, hemorrhage, and polycythemia vera (a disease characterized by an absolute increase in erythrocyte mass and total blood volume).

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2305, Jan. 14, 2000]

§ 862.1135 C-peptides of proinsulin test system.

(a) *Identification.* A C-peptides of proinsulin test system is a device intended to measure C-peptides of proinsulin levels in serum, plasma, and urine. Measurements of C-peptides of proinsulin are used in the diagnosis and treatment of patients with abnormal insulin secretion, including diabetes mellitus.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2305, Jan. 14, 2000]

§ 862.1140 Calcitonin test system.

(a) *Identification.* A calcitonin test system is a device intended to measure the thyroid hormone calcitonin (thyrocalcitonin) levels in plasma and serum. Calcitonin measurements are used in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism (excessive activity of the parathyroid gland).

(b) *Classification.* Class II.

§ 862.1145 Calcium test system.

(a) *Identification.* A calcium test system is a device intended to measure the total calcium level in serum. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases,

chronic renal disease and tetany (intermittent muscular contractions or spasms).

(b) *Classification.* Class II.

§ 862.1150 Calibrator.

(a) *Identification.* A calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens. (See also § 862.2 in this part.)

(b) *Classification.* Class II.

§ 862.1155 Human chorionic gonadotropin (HCG) test system.

(a) *Human chorionic gonadotropin (HCG) test system intended for the early detection of pregnancy*—(1) *Identification.* A human chorionic gonadotropin (HCG) test system is a device intended for the early detection of pregnancy is intended to measure HCG, a placental hormone, in plasma or urine.

(2) *Classification.* Class II.

(b) *Human chorionic gonadotropin (HCG) test system intended for any uses other than early detection of pregnancy*—(1) *Identification.* A human chorionic goadotropin (HCG) test system is a device intended for any uses other than early detection of pregnancy (such as an aid in the diagnosis, prognosis, and management of treatment of persons with certain tumors or carcinomas) is intended to measure HCG, a placental hormone, in plasma or urine.

(2) *Classification.* Class III.

(3) *Date PMA or notice of completion of a PDP is required.* As of the enactment date of the amendments, May 28, 1976, an approval under section 515 of the act is required before the device described in paragraph (b)(1) may be commercially distributed. See § 862.3.

§ 862.1160 Bicarbonate/carbon dioxide test system.

(a) *Identification.* A bicarbonate/carbon dioxide test system is a device intended to measure bicarbonate/carbon dioxide in plasma, serum, and whole blood. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

(b) *Classification.* Class II.

§ 862.1163 Cardiac allograft gene expression profiling test system.

(a) *Identification.* A cardiac allograft gene expression profiling test system is a device that measures the ribonucleic acid (RNA) expression level of multiple genes and combines this information to yield a signature (pattern, classifier, index, score) to aid in the identification of a low probability of acute cellular rejection (ACR) in heart transplant recipients with stable allograft function.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Cardiac Allograft Gene Expression Profiling Test Systems.'' See § 862.1(d) for the availability of this guidance document.

[74 FR 53885, Oct. 21, 2009]

§ 862.1165 Catecholamines (total) test system.

(a) *Identification.* A catecholamines (total) test system is a device intended to determine whether a group of similar compounds (epinephrine, norepinephrine, and dopamine) are present in urine and plasma. Catecholamine determinations are used in the diagnosis and treatment of adrenal medulla and hypertensive disorders, and for catecholamine-secreting tumors (pheochromo-cytoma, neuroblastoma, ganglioneuroma, and retinoblastoma).

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2305, Jan. 14, 2000]

§ 862.1170 Chloride test system.

(a) *Identification.* A chloride test system is a device intended to measure the level of chloride in plasma, serum, sweat, and urine. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

(b) *Classification.* Class II.